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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,488	12/10/2003	Yaron Ilan	59046.44 Enz-64 (D3)	7675

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
05/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,488	ILAN ET AL.	
	Examiner	Art Unit	
	EMILY M. LE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-52,55-57 and 59-62* is/are pending in the application.

4a) Of the above claim(s) *61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-52,55-57,59,60 and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-49, 53-54 and 58 are cancelled. Claims 50-52, 55-57 and 59-62 are pending. Claim 61 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/02/2005. Claims 50-52, 55-57, 59-60 and 62 are under examination with independent claim 50 amended.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites a dependency to claim 58. Claim 58 has been cancelled by Applicant in the most recent submission. In the absence of a dependency to a pending claim, it is unclear what Applicant intends to encompass by claim 59. For the purpose of advancing examination, claim 59 is interpreted to recite a dependency to claim 50, which provides proper antecedent basis for the recitation "infection".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 50-52 and 55-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Motoki et al.,[1] as evidenced by Elgert et al.[2]

In response to the rejection, Applicant amended the claims with the recitation "comprising an infection or an immune dysfunction". That is the claims require the immune response induced by the metabolite be part of a disease comprising an infection or an immune dysfunction. In following this amendment, Applicant argues that Motoki et al. teaches cancer, not an infection or an immune dysfunction.

Applicant's argument has been considered, however, it is not persuasive. While Motoki et al. teaches the administration of the mammalian metabolite to subjects that have cancer. Motoki et al. also teaches that the metabolite is immunostimulatory. Elgert et al. teaches that tumor/cancer induces immune dysfunction in a subject. In the instant case, the subjects of Motoki et al. have cancer. The subjects inherently have

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[1] Motoki et al. Immunostimulatory and antitumor activities of monoglycosylceramides having various sugar moieties. Biol. Pharm. Bull., November 1995, Vol. 18, No. 11, 1487-1491.
[2] Elgert et al. Tumor-Induced immune dysfunction: the macrophage connection. Journal of Leukocyte Biology, 1998, Vol. 64, 275-290.

tumor induced immune dysfunction. The subjects therefore have a disease that comprises an immune dysfunction. The claims remain anticipated by Motoki et al.

The claims are directed to a process comprising the administration of a glycolipid to a diseased subject, wherein the disease comprises an infection or an immune dysfunction. Claim 51, which depends on claim 50, requires the administration to modulate the cellular, humoral or cytokine elements of the immune system of the subject. Claim 52, requires the modulation to be specific or non-specific. Claim 55, which depends on claim 50, requires the glycolipid to comprise a monosaccharide ceramide. Claim 56, which depends on claim 55, requires that the monosaccharide ceramide to be beta-glucosylceramide or beta-galactosylceramide. Claim 57, which depends on claim 50, requires the administration be intravenous, intra-muscular, subcutaneous, intraperitoneal or oral. Claim 58, which depends on claim 50, requires the subject to have cancer.

Motoki et al. teaches a process comprising the administration of a glycolipid to a diseased subject. The glycolipid administered, subcutaneously, by Motoki et al. are beta-glucosylceramide or beta-galactosylceramide, monosaccharide ceramide. The subject of Motoki et al. has cancer. Motoki et al. also demonstrates that the glycolipid is immunostimulatory. In the instant case, Motoki et al. teaches the claimed invention. Motoki et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 50-52, 55-57, 59-60 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motoki et al., as applied to claims 50 and 58, in view of Ogawa et al.[3]

In response to the rejection, Applicant argues that claimed invention is not obvious over the cited references. Applicant submits that based on the title of the reference "Glycolipid Analogs", the reference does not describe mammalian intermediary metabolite.

Applicant also notes that all the experiments disclosed by Ogawa et al. incorporates the use of artificial or non-natural glycolipids rather than natural glycolipids, and Ogawa et al. is focused on receptor binding and not the modification of immune response. Applicant additionally submits that Motoki et al. reference do not focus on viruses or their receptors. Therefore, Applicant argues that one of skill in the art would have no motivation to combine these references.

Applicant's arguments have been considered, however, it is not found persuasive. While Applicant is correct to note that the title of the Ogawa et al. references is "Glycolipid Analogs", Applicant is incorrect to argue that reference does not teach the mammalian intermediary metabolite recited in the claims. At lines 35-50, column 1, Ogawa et al. teaches of mammalian intermediary metabolites. The mammalian intermediary metabolites that Ogawa et al. teaches are beta-glucosylceramide and beta-galactosylceramide.

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, the motivation to combine the cited references is clearly detailed in the rejection.

Both references teach of glycolipids. Both Ogawa et al. and Motoki et al. disclose of the sphingoid polyalkylamine conjugates recited in Applicant's claims. Ogawa et al. teaches that glycolipids, including the conjugate recited in the claims, closely relate to receptor functions for physiologically active substances and important cell functions, such as generation, proliferation, differentiation or immune reactions, via intercellular recognition and interactions. Ogawa et al. also establishes that it is known that glycolipids play a role as a receptor in the host side in the infection with bacteria and viruses. [Lines 55-61, column 1, in particular.] Based on this knowledge, Ogawa et al. discloses the use of glycolipids to inhibit viral infections. Thus, at the time the invention was made, Ogawa et al. establishes that glycolipids have antiviral activities. Additionally, Motoki et al. establishes that the conjugate recited in the claims is immunostimulatory. In the instant case, the Motoki et al. clearly teaches the

[3] Ogawa et al. U.S. Patent No. 5861520, published January 19, 1999.

administration of the conjugate to induce an immune response. Combining the teachings of Motoki et al. and Ogawa et al., one of ordinary skill in the art, at the time the invention was made would be motivated to administer the conjugate to a virally infected subject to inhibit viral infection or to induce an immune response against the infection.

Claims 50-52 and 55-57 are discussed above. Claim 59, which depends on claim 50, requires the infection to be viral or bacterial. Claim 60, which depends on claim 59, requires the viral infection to be HBV, HCV, or HIV.

The significance of Motoki et al., as applied to claims 50-52 and 55-57 is provided above. The subject of Motoki et al. is not a virally infected subject, including humans. However, at the time the invention was made, Ogawa et al. also teaches that glycolipids, including beta anomers of the glucosylceramide and galactosylceramides closely relates to receptor functions for physiologically active substances and important cell functions, such as generation, proliferation, differentiation or immune reactions, via intercellular recognition and interactions. Ogawa et al. also establishes that it is known that glycolipids play a role as a receptor in the host side in the infection with bacteria and viruses. [Lines 55-61, column 1, in particular.]Based on this knowledge, Ogawa et al. discloses the use of glycolipids to inhibit viral infections. Thus, at the time the invention was made, Ogawa et al. establishes that glycolipids have antiviral activities.

Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to administer the glycolipids taught by Motoki et al. to a virally infected subject, including human and those infected with HBV, HCV or

HIV. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to inhibit viral infection or to induce an immune response against the infection. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the antiviral activities of glycolipids has been demonstrated and established by Ogawa et al.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. In response to the provisional rejection of the claims on the ground of nonstatutory obviousness-type double patenting, Applicant requested that the rejection be held in abeyance until the finding of allowable subject matter.

Applicant's request has been noted, however, until the rejection is properly addressed, it is maintained on the record.

10. Claims 50-52, 55-57, 59-60 and 62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-6, 9 and 11 of copending Application No. 10/375906. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications are directed at a process comprising the administration of a glycolipid to a virally infected subject.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LE whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on (571) 272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/
Primary Examiner, Art Unit 1648

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